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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,727	08/24/2001	Reiner L. Gentz	PF454P2	3532

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EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,727	GENTZ ET AL.	
	Examiner	Art Unit	
	Eileen O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-147* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-147* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 49-147 are pending in the instant application. Claims 124-147 have been added as requested by Applicant in the Paper filed July 19, 2005.

New Rejections and Objections

Claim Objections

2. Claim 131 is objected to because of the following informalities: the article "the" should be inserted between "neutralizes" and "inhibitory" to be grammatically correct. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 126, 133, 136 and 137 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventor(s), at the time the application was filed, had possession of the claimed invention.

3.1 Claims 126 and 133 encompass antibodies to the polypeptide of SEQ ID NO: 2, wherein the antibodies are monovalent. However, there is no disclosure of monovalent antibodies in the specification or claims as originally filed, and this is therefore new matter.

3.2 Claims 136 and 137 encompass antibodies to the polypeptide of SEQ ID NO: 2, wherein the antibodies are the specific monoclonal (a) the 4C4.1.4 monoclonal antibody produced by the hybridoma cell line deposited as ATCC accession number HB-12573, (b) the 5C4.14.7 monoclonal antibody produced by the hybridoma cell line deposited as ATCC accession number HB-12574, (c) the 11C5.2.8 monoclonal antibody produced by the hybridoma cell line deposited as ATCC accession number HB-12572, (d) the 8D3.1.5 monoclonal antibody produced by the hybridoma cell line deposited as ATCC accession number HB-12571, and (e) the 4B7.1.1 monoclonal antibody produced by the hybridoma cell line deposited as ATCC accession number HB-12575, and none of these monoclonal antibodies or cell lines were in the specification or claims as originally filed, and this is therefore new matter.

Maintained Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 49-123 remain rejected, and new claims 124-147 are rejected, under 35 U.S.C. 102(e) as being anticipated by Ashkenazi et al., U.S. Patent No. 6,764,679, effective priority date Sept. 18, 1998, for reasons of record in the previous office action, mailed May 9, 2005, at pages 3-4.

New claims 124-147 encompass antibodies to the protein of SEQ ID NO: 2, wherein the antibody inhibits binding of LIGHT to the protein, the antibody is polyclonal, monoclonal, chimeric, human or monovalent, comprises a Fab or (ab')2 fragment, the antibody is expressed in a recombinant host cell selected from the group consisting of a CHO cell, yeast cell and E. coli, the antibody is the following monoclonal antibody or binds to the same epitope as the following antibody selected from the group consisting of (a) the 4C4.1.4 monoclonal antibody produced by the hybridoma cell line deposited as ATCC accession number HB-12573, (b) the 5C4.14.7 monoclonal antibody produced by the hybridoma cell line deposited as ATCC accession number HB-12574, (c) the 11C5.2.8 monoclonal antibody produced by the hybridoma cell line deposited as ATCC accession number HB-12572, (d) the 8D3.1.5 monoclonal antibody produced by the hybridoma cell line deposited as ATCC accession number HB-12571, and (e) the 4B7.1.1 monoclonal antibody produced by the hybridoma cell line deposited as ATCC accession number HB-12575, the antibody neutralizes the inhibitory effect of the protein consisting of amino acids 1-215 of SEQ ID NO: 2 on Fas ligand-induced in one or more mammalian cells which may be colon cancer or lung cancer cells, the antibody decreases the binding of amino acids 31-300 of the protein of SEQ ID NO: 2 to a TNF family ligand which may be Fas ligand or AIM-II, and the antibody antagonizes inhibition of apoptosis mediated by amino acids 31-300 of the protein of SEQ ID NO: 2.

Ashkenazi et al. discloses a protein (SEQ ID NO: 1) that is identical to the protein of SEQ ID NO: 2 of the instant invention, and antibodies to the protein (see previous office action at pages 3-4. Ashkenazi et al. also teach that the antibody inhibits binding of LIGHT to the protein, the antibody is polyclonal, monoclonal, chimeric, human or monovalent, comprises a

Fab or (ab')2 fragment, the antibody is expressed in a recombinant host cell selected from the group consisting of a CHO cell, yeast cell and E. coli, the antibody is the monoclonal antibody or binds to the same epitope as the monoclonal antibody selected from the group consisting of (a) the 4C4.1.4 monoclonal antibody produced by the hybridoma cell line deposited as ATCC accession number HB-12573, (b) the 5C4.14.7 monoclonal antibody produced by the hybridoma cell line deposited as ATCC accession number HB-12574, (c) the 11C5.2.8 monoclonal antibody produced by the hybridoma cell line deposited as ATCC accession number HB-12572, (d) the 8D3.1.5 monoclonal antibody produced by the hybridoma cell line deposited as ATCC accession number HB-12571, and (e) the 4B7.1.1 monoclonal antibody produced by the hybridoma cell line deposited as ATCC accession number HB-12575, the antibody neutralizes the inhibitory effect of the protein consisting of amino acids 1-215 of SEQ ID NO: 2 on Fas ligand-induced in one or more mammalian cells which may be colon cancer or lung cancer cells, the antibody decreases the binding of amino acids 31-300 of the protein of SEQ ID NO: 2 to a TNF family ligand which may be Fas ligand or AIM-II, and the antibody antagonizes inhibition of apoptosis mediated by amino acids 31-300 of the protein of SEQ ID NO: 2 (see claims). Although Ashkenazi et al. does not teach that AIM-II is a ligand for the protein of SEQ ID NO: 1, absent evidence to the contrary, the antibodies of Ashkenazi et al. would also decrease the binding of AIM-II. Therefore, Ashkenazi et al. anticipates the claims.

In the response, Applicants did not traverse or discuss the rejection, and it is maintained for reasons of record in the previous office action.

Conclusion

5. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (571) 272-0829.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner

EILEEN B. O'HARA
PATENT EXAMINER